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K120823
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FRESENIUS MEDICAL CARE

BVM Hemodialysis Blood Tubing Set
Traditional 510(k) Notification

510(k) summary

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content in this 510(k) summary has been provided in conformance with 21 CFR Part 807.92

A. Submitter's Information

Name:	Fresenius Medical Care North America (FMCNA)
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Contact Person:	Denise Oppermann, Senior Director Regulatory Affairs – Devices
Date of Preparation:	3/16/2012

B. Device Name

Trade Name:	Blood Volume Monitor (BVM) Hemodialysis Blood Tubing Set with Attached Priming Set and Transducer Protectors
Common Name:	Blood Tubing Sets (Sterile Fluid Path)
Product Code/Classification Panel:	FJK / Gastroenterology-Urology
Classification Name:	Set, Tubing, Blood, With And Without Anti-Regurgitation Valve 21 CFR 876.5820

C. Legally Marketed Predicate Device (unmodified devices)

Nikkline Blood Tubing Lines with Transducer Protectors (K082719)

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D. Device Description

The Fresenius Blood Volume Monitor (BVM) Hemodialysis Blood Tubing Set with Attached Priming Set and Transducer Protectors, Catalog number 03-2795-7 (BVM Bloodline) is designed to work with Fresenius 2008 Series Hemodialysis Machines equipped with a BVM Module.

The bloodline is a part of the extracorporeal circuit by which blood is transported from the patient through a hemodialyzer and back to the patient. The pump segment of the bloodline interfaces with the pump rotor mechanism of the hemodialysis machine which drives the flow of blood through the circuit. The bloodline contains interfaces to the machine safety mechanisms to ensure proper operation. These include transducer monitor lines for arterial and venous pressure monitoring, as well as a venous chamber for the detection of air in the blood path.

E. Indications for Use

The Blood Volume Monitor (BVM) Hemodialysis Blood Tubing Set with Attached Priming Set and Transducer Protectors is a single use, disposable arterial and venous bloodline set intended to provide extracorporeal access during hemodialysis. The set is intended for use with a prescribed hemodialyzer.

The BVM Hemodialysis Blood Tubing Set is intended for acute and chronic hemodialysis therapy. The set is intended for use with the Fresenius 2008 Series Hemodialysis Machines equipped with a BVM Module for monitoring patient blood volume during hemodialysis.

F. Technological Characteristics

The BVM Bloodline and the Nikkline Blood Tubing Lines with Transducer Protectors (K082719) have equivalent technological characteristics. The BVM Bloodline and the Nikkline share equivalent:

- Intended Use – provides extracorporeal access during hemodialysis
- Design/Configuration
- Basic Scientific Technology – peristaltic pump, pressure monitoring capabilities, air capture chambers
- Sterility – single use, nonpyrogenic
- Materials – primary materials of polyvinyl chloride (PVC) and polypropylene (PP).

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G. Performance Data

Testing was selected through the application of a risk management process, appropriate guidance documents and relevant standards. The results of the validation and verification testing have provided a sound basis for comparison to the predicate bloodline. The following are an example of some of the tests performed to support the determination of substantial equivalence:

- Biological safety – biocompatibility testing
- Sterility and nonpyrogenicity testing
- Structural integrity – pressure and pull testing
- Performance testing of connectors (hemodialyzer, vascular access device and ancillary components) - pressure/dimensional
- Needle access ports- pressure testing after repeated use
- Transducer protectors- pressure testing
- Endurance testing of the complete bloodline using specified hemodialysis machines
- Clamp testing- ability to occlude and effects of repeated use
- Usability evaluation

H. Conclusion

Based on a cumulative review of the verification and validation testing, the performance of the BVM Bloodline is substantially equivalent to the predicate Nikkline (K082719) and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 15 2012

Ms. Denise Oppermann
Senior Director Regulatory Affairs, Devices
Fresenius Medical Care North America
920 Winter Street
WALTHAM MA 02451

Re: K120823
Trade/Device Name: Blood Volume Monitor (BVM) Hemodialysis Blood Tubing Set with Attached Priming Set and Transducer Protectors
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FJK
Dated: March 16, 2012
Received: March 21, 2012

Dear Ms. Oppermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for use statement

510(k) Number (if known): K120823

Device Name:

Blood Volume Monitor (BVM) Hemodialysis Blood Tubing Set with Attached Priming Set and Transducer Protectors

Indications for Use:

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☒ Prescription Use (Per 21 CFR 801 Subpart D) AND/OR ☐ Over-the-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

15 June 2012

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120823